

WILMERHALE

Via ECF & Federal Express

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The Honorable F. Dennis Saylor, IV
United States District Judge
United States District Court
Donohue Federal Building
595 Main Street
Worcester, MA 01608

Re: *Abbott GmbH & Co., KG et al. v. Centocor Ortho Biotech, Inc., et al.*, C.A. No. 4:09-cv-11340

Dear Judge Saylor:

I am writing on behalf of Abbott in response to Ms. Elderkin's letter dated July 11, 2012, regarding Centocor's proposal on the manner in which to resolve the issue of willful infringement.

We disagree with many of Ms. Elderkin's comments about the Federal Circuit's decision in *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assoc., Inc.*, No. 2012-1510 (Fed. Cir. June 14, 2012), and the willfulness issues in the case. Nevertheless, Abbott has no objection to bifurcation, under Fed. R. Civ. P. 42(b), as follows: the issue of liability would be tried to the jury first; if the jury were to find liability, the same jury would immediately hear and decide the issues of damages and willful infringement. Abbott objects to bifurcation if the only issue separately tried is the issue of willfulness and objects to any bifurcation that would delay the ultimate resolution of the case, such as additional proceedings before a different jury. We also believe that in light of the pretrial schedule, an inappropriate burden would be placed on the Court and the parties to try to resolve the issue of willfulness by new summary judgment briefing prior to the trial.

Although *Bard* clarified the role of the Court and jury in deciding willfulness, Centocor goes too far in suggesting that it mandates any particular procedural mechanism in this case or any other. *Bard* holds that the first prong of *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007), while ultimately an issue of law, can be one based on facts that are appropriately submitted to the jury. *Bard*, Slip op. at 9. In that respect, it is no different than numerous other issues of patent law that are ultimately for the Court, although based on underlying facts. See, e.g., *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (obviousness is issue of law based on underlying facts); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (enablement is issue of law based on underlying facts). Such issues are routinely submitted to the jury (frequently using a special verdict form) with the ultimate issue ruled on pursuant to motions for judgment as a matter of law ("JMOLs"). In this case and most others, the issue of willfulness should be decided and resolved in the same manner.

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Centocor is also incorrect in suggesting that the evidence relevant to willfulness and the evidence relating to liability do not overlap. For example, it is easy enough to imagine an admission of infringement by an accused infringer that would simultaneously be relevant to the liability and both prongs of *Seagate*. As another example drawn from the facts in this case, Centocor's conduct in the interference is relevant to liability and both prongs for willfulness. In the interference, Centocor attempted to invalidate Abbott's claims based on obviousness by relying on "phage display" prior art. (See D.I. 208-8, Oylo Decl., Ex. 24, Centocor Mot. 1, at 18-20.) In this case, it apparently intends to rely on such art again, and also on art directed to the use of transgenic mice. (See D.I. 209-17, Pearson Decl., Ex. 17, Siegel Invalidity Rep., dated May 16, 2012, ¶ 191.) The fact that the phage display art was before the Patent Office in the interference is relevant to validity. See *Sciele Pharma Inc. v. Lupin Ltd.*, ___ F.3d ___, 2012 WL 2520908, at *5 (Fed. Cir. July 2, 2012). The fact that Centocor did not even rely on the transgenic mouse prior art before the PTO is an implicit admission of its irrelevance and should be considered in deciding the "objective prong" of *Seagate*. And the fact that Centocor proceeded with infringement notwithstanding the PTO's denial of Centocor's obviousness defense is relevant to the second prong of *Seagate* because it shows that Centocor knew that there was an objectively high risk that it infringed a valid patent.

Finally, and no doubt needless to say, Abbott also disagrees with Centocor's characterization of the merit of its defenses. For example, Centocor's belated claim of non-infringement based on the argument that it does not sell a "human antibody" in the face of innumerable admissions that its antibody is human would appear to be a textbook example of a defense that does not rebut the inference that Centocor acted recklessly in the face of an objectively high likelihood that it infringed.

Centocor's primary ground for seeking bifurcation appears to be that, in the absence of bifurcation, Centocor would have to "present evidence of the reasonableness of its behavior" and that this would "be confusing to the jury and would unfairly predispose it to believe that Centocor's defenses were not reasonable." (D.I. 355, Centocor Letter, dated July 11, 2012, at 4.) But Centocor does not identify the evidence to which it is referring or why it would be prejudicial and confusing to the jury.

Be that as it may, Abbott does believe the case may be appropriately sequenced between, on the one hand, liability and, on the other hand, damages and willfulness. In its letter to Abbott dated June 29, Centocor suggested that it would be willing to stipulate to infringement of the several claims still in the case that were not subject to the Court's summary judgment ruling of infringement. If so, then the first phase of the case could be validity only, with obvious benefits in terms of both jury comprehension and speed. The second phase would then be damages and willfulness, to the extent that there is a jury verdict in Abbott's favor. The *Bard* inquiry by the court would be made on JMOL. In bifurcated proceedings, courts routinely try damages and willfulness together for the obvious reason that neither issue has to be reached if there is no

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verdict on liability in favor of the plaintiff. *See, e.g., Mike's Train House, Inc. v. Broadway Ltd. Imports, LLC*, No. 09-2657, 2011 U.S. Dist. LEXIS 27550, at *9 (D. Md. Mar. 17, 2011); *Patent Holding Co. v. TG (USA) Corp.*, No. 96-74721, 1997 U.S. Dist. LEXIS 22571, at *6-7 (E.D. Mich. Dec. 2, 1997); *Amsted Indus. Inc. v. Nat'l Castings, Inc.*, No. 88 C 924, 1990 U.S. Dist. LEXIS 8553, at *4-5 (N.D. Ill. July 9, 1990). In addition, such an approach would preclude Centocor from introducing, among other things, evidence of MACE events associated with Abbott's IL-12 antibody. The Court has already ruled this issue is only relevant to the issue of damages. (D.I. 341, Am. Mem. & Order, dated May 4, 2012, at 72-75.) In contrast to the unnamed prejudice identified by Centocor in its letter, evidence of MACE will clearly prejudice Abbott on the issue of liability, and bifurcation of liability and damages will eliminate the possibility of this prejudice.

Bifurcation in this manner would moot Centocor's request that the Court permit briefing on the issue of willfulness prior to trial. Neither party briefed the "reasonableness" issue during summary judgment proceedings, and to do so now would impose a substantial burden on the Court and the parties during a period that is already filled with activities necessary to prepare the case for trial. The Court will be in a far better position to assess the issue of "objective" reasonableness at the conclusion of trial when it can rule on that issue pursuant to a motion for judgment as a matter of law.

We look forward to discussing these issues at the conference scheduled for July 18.

Respectfully yours,

A handwritten signature in black ink that reads "William F. Lee" followed by a vertical line and the initials "RW".

William F. Lee

Enclosures

cc: Diane B. Elderkin, Esq. (via email)
Barbara L. Mullin, Esq. (via email)